## 7. 510(K) SUMMARY

### *7.1.1 Assigned 510(k) Number*

The assigned 510(k) number is K120663

### *7.2 Sponsor Name and Address*

Dako North America, Inc
6392 Via Real
Carpinteria, CA 93013
Phone: 1 805 566 6655
Fax: 1 805 566 6688

Establishment registration No: 2022180

### *7.3 Contact*

Xiaolei Xu, Ph.D.
Regulatory Affairs Manager
E-mail: xiaolei.xu@dako.com
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Fax: 1 805 566 6688

***7.4 Summary Prepared*** February 28, 2012

***7.5 Summary Revised*** Feb 4, 2013

### *7.6 Device Name(s)*

| | |
|---|---|
| Trade name(s) | Dako Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1,<br>FLEX, Ready- to-Use (RTU) Link<br>Product code: IR084 |
| Common name(s) | Dako Anti-Human ER α, Clone EP1 |
| Classification: | Class II (21 CFR 864.1860) |

### 7.7 *Predicate Device:*

ER α component of the Dako ER/PR pharmDx™ Kit (K042884)

### 7.8 *Device Description*

Dako Monoclonal Rabbit Anti-Human Estrogen Receptor (ER) α, Clone EP1 (Dako Anti-Human ER α, clone EP1) antibody is utilized to perform a semi-quantitative immunohistochemical (IHC) assay to identify estrogen receptor (ER) expression in human breast cancer tissues routinely processed and paraffin-embedded for histological examination. The ER α antibody is available in Ready-to-Use (RTU) format and is optimized for use with Dako Automated stainer Autostainer Link 48. The RTU Monoclonal Rabbit Anti-Human Estrogen Receptor (ER) α, Clone EP1 is provided in one vial of ready-to-use monoclonal rabbit antibody contains 12 ml of reagent provided in liquid form in a buffer containing stabilizing protein and 0.015 mol/L sodium azide. The working Ig concentration of the antibody is approximately 3.7 µg/mL. Total protein concentration is approximately 10mg/mL.

### 7.9 *Intended Use:*

For in vitro diagnostic use.
FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use, (LINK), is intended for use in immunohistochemistry with EnVision™ FLEX, High pH visualization kit together with Autostainer Link 48 to semi-quantitatively detect human estrogen receptor in formalin-fixed, paraffin-embedded tissue sections of human breast cancer. The antibody labels estrogen receptor α-positive cells and is useful in the assessment of estrogen receptor status in human breast carcinomas.

The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

### 7.10 *Substantial Equivalence*

Dako Anti-Human ER α, clone EP1 Antibody IHC assay is substantially equivalent to the ER α component of the Dako ER/PR pharmDx™ Kit. Both products specifically bind to estrogen receptor proteins located in the nuclei of cells, these products require similar detection chemistry principles for visualization of the product, and both aid in

the prognosis of breast carcinoma. The difference in visualization between the predicate device and Anti-human ER α Antibody, Clone EP1 does not introduce new issues of safety and effectiveness.

### *7.11 Performance Characteristics:*

Performance characteristics evaluated in support of the Dako Anti-Human ER α, clone EP1 IHC assay include results on specificity, sensitivity, reproducibility, and concordance testing. Results of all testing conducted have demonstrated a substantial degree of equivalency to the predicate device listed above.

Therefore, based on the information provided in this premarket notification, Dako concludes that the device listed above is safe, effective and substantially equivalent to the predicate device in the indication for use, device design, materials, operational principles, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2013

Dako North America, Inc
c/o Dr. Xiaolei Xu
Regulatory Affairs Manager
6392 Via Real
Carpinteria, California 93013

Re: k120663

Trade/Device Name: FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use (Link)

Regulation Number: 21 CFR §864.1860
Regulation Name: Immunohistochemistry reagents and kits
Regulatory Class: II
Product Code: MYA
Dated: January 16, 2013
Received: January 24, 2013

Dear Dr. Xu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Reena Philip -S

for

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K120663

Device Name:

Monoclonal Rabbit Anti- Human Estrogen Receptor α, Clone EP1
FLEX Ready-to-Use (Link)
Product Code IR084

Indications For Use:

For in vitro diagnostic use.

FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor α, Clone EP1, Ready-to-Use, (LINK), is intended for use in immunohistochemistry with EnVision™ FLEX, High pH visualization kit together with Autostainer Link 48 to semi-quantitatively detect human estrogen receptor in formalin-fixed, paraffin-embedded tissue sections of human breast cancer. The antibody labels estrogen receptor α-positive cells and is useful in the assessment of estrogen receptor status in human breast carcinomas.

The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna Rowe
Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) K120663